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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/647,599 | 10/03/2000 | Leigh T Canham | 124-796 | 1219 |

7590 10/22/2002
Nixon & Vanderhye
1100 North Glebe Road 8th Floor
Arlington, VA 22201-4714

EXAMINER

WARE, TODD

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/647,599

Applicant(s)

CANHAM ET AL.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34,35,54-57,59-71,76-95,103-108 and 113-133 is/are pending in the application.
- 4a) Of the above claim(s) 34,35,54-57,59-71,76-95 and 103-108 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 113-133 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and response filed 7-17-02 is acknowledged. Claims 1-33, 36-39, 42-53, 72-75, 96-102, and 109-112 have been canceled and new claims 113-133 have been added as requested.

Election/Restrictions

1. This application contains claims 34-35, 54-57, 59-71, 76-95, and 103-108 drawn to an invention nonelected without traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

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published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 113-115, 117, 120-121 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Canham et al (WO 97/06101; hereafter '101).

4. '101 discloses resorbable porous polycrystalline silicon implants that release active agents such as calcium. The implants of '101 are disclosed as biocompatible and therefore meet the new limitation of the instant claims requiring that the implant is tissue compatible. Furthermore, the polycrystalline silicon appears to be the same as that of the instant claims which results in the implants having the same properties, since a chemical composition and its properties are inseparable and the properties applicant discloses are necessarily present (see MPEP 2112.01).

Response to Arguments

5. Applicant's arguments filed 7-17-02 as applied to the new rejection have been fully considered but they are not persuasive. Applicant argues that the implant of '101 is not associated with a beneficial substance. In response, it is submitted that the implant of '101 delivers the beneficial substance calcium. Applicant also argues that the implants of '101 are not tissue compatible, reciting page 14, lines 17-19 of the instant specification and page 12, lines 31-33 of '101. This is not completely understood. Apparently, applicant is arguing that '101 only discloses *in vitro* tests of the implants, while the instant claims are supported by *in vivo* application. Applicant also asserts that a difference between the silicon of '101 and the instant claims can be therefore

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deduced. However, no direct comparisons between the porous polycrystalline silicon of '101 and the instant implants to ascertain any different elemental components of the implants has been provided. '101 discloses that the implants are resorbable. The text indicated by applicant only demonstrates a difference in the rate of dissolution. Indeed, applicant's data are taken from comparisons at 0, 1, 4, and 12 weeks, while this section of '101 provides data taken from 1 day.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 113-121 and 128-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canham et al (WO 97/06101; hereafter '101).

9. '101 teaches resorbable porous polycrystalline silicon implants that release active agents such as calcium. The implants of '101 are disclosed as biocompatible and therefore meet the new limitation of the instant claims requiring that the implant is tissue compatible. Furthermore, the polycrystalline silicon appears to be the same as that of the instant claims which results in the implants having the same properties, since a chemical composition and its properties are inseparable and the properties applicant discloses are necessarily present (see MPEP 2112.01).

Response to Arguments

10. Applicant's arguments filed 7-17-02 as applied to the new rejection have been fully considered but they are not persuasive. Applicant argues that the language bridging pages 16 and 17 of '101 would discourage the skilled person from performing experiments to investigate tissue compatibility in connection with resorbable silicon for drug delivery since tissue compatibility is associated with formation of a protective barrier that could inhibit the delivery of the drug. However, '101 only refers to reduction of the physiological effects of the silicon. There is no teaching that effects no longer occur. The tissue barrier does not completely block the effects and agent diffuses through the barrier. Applicant also argues that '101 states that it is impossible to determine ultimate tissue compatibility on the basis that it is not possible to predict the response of a mammalian body to resorbable silicon. However, applicant does not provide comparisons between the porous polycrystalline silicon of '101 and the instant

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implants to ascertain any different elemental components of the implants. Furthermore, the teaching of '101 as a whole suggests to one skilled in the art that the implants of '101 are biocompatible and therefore tissue compatible. '101 provides previous evidence of biocompatibility for such implants and therefore it appears that the quoted paragraph is directed toward certain applications. In other words, it appears that this paragraph admits that there are certain applications where further experimentation to determine compatibility is required. However, the instant recitation of "tissue compatible" encompasses any tissue compatibility and does not specifically set for the type of tissue the material is compatible with. Accordingly, it is the position of the examiner that applicant's quotation of '101 is taken out of context. Applicant's emphasis of the biological properties of silicon and the ease of confusion between the different kinds of silicon is noted. From this text, it appears applicant is suggesting that '101 discloses/teaches only bioactive silicon and not resorbable, tissue compatible silicon. However, it is the position of the examiner that the implants of '101 teach porous crystalline silicon (see page 6, lines 5-24; page 13, lines 25-31; page 14, lines 1-23; page 17, lines 4-14; page 20, line 21-page 21, line 12). Such consideration of '101 as a whole suggests that the implants have a polycrystalline silicon having microstructures resulting in properties of microstructures taught in '101.

11. Claims 113-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canham et al (WO 97/06101; hereafter '101) in view of Heimke et al (3,919,723; hereafter '723).

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12. '101 is relied upon for all that it teaches as previously stated. '101 does not teach bringing the implant in contact with molten beneficial substance.

13. '723 is relied upon for teaching of loading silicon implants with molten calcium in combination with an oxidant. *Cl. 122 oxidant effecting*

14. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '101 and '723 with the motivation of controlling the release of substance from the implant.

Response to Arguments

15. Applicant's arguments filed 7-17-02 as applied to '101 and as addressed in paragraph 10 of the instant Office Action are again reiterated here.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
October 18, 2002

THURMAN K PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600